

## **REMARKS**

### **I. Status of the Application**

Claims 1-37 are presently pending in the application. Applicant gratefully acknowledges that the rejection of claims 1, 15-16, 19-20, 29-30 and 34-36 under 35 U.S.C. § 102(b) as being anticipated by Scheicher (U.S. Patent No. 4,278,630) has been withdrawn due to Applicant's amended claim 1. Applicant also gratefully acknowledges that claims 8, 33 and 37 would be allowable if rewritten in independent form. Claim 13 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Scheicher (U.S. Patent No. 4,278,630). Claims 6-7 and 11-12 stand rejected under 35 U.S.C. § 102(b) as being anticipated by WO 86/04088. Claims 13 and 14 stand rejected under 35 U.S.C. § 102(b) as being anticipated by WO 98/47465. Claims 1, 3-6, 9-10, 15-32 and 34-36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 86/04088.

Applicant has amended the claims to more clearly define and distinctly characterize the Applicant's novel invention. Claim 1 has been amended to specify that the sintered scaffold material has a pore size sufficient to allow ingrowth of tissue. Support for this amendment can be found throughout the specification, for example at page 8, lines 11-13, which states that the porous scaffold sintered preferably from bioactive glass fibers is able to form a matrix into which cartilage tissue can grow. Claim 13 has been amended to delete the term "or ceramic," so that the claim recites "glass fibers." Support for glass fibers can be found throughout the specification as filed, for example at page 1, lines 3-8. Claims 25 and 27 have been amended to specify "bioactive glass fibers." Support can be found throughout the specification, for example at page 8, lines 22-33 and at page 10, lines 15-17. Claims 25 and 27 have also been amended to specify scaffold material pore size sufficient to allow ingrowth of tissue. Support can be found

at page 8, lines 11-13. Multiple dependent claims 8, 33 and 37 have been amended into independent form, including all of the limitations of the first base claim and any intervening claims. New claims 50-52 have been added as the independent forms of multiple dependent claims 8, 33 and 37, including all of the limitations of the second base claim and any intervening claims.

Applicant respectfully submits that the amendments presented herein add no new matter, so do not raise new issues requiring further search. Applicant respectfully requests entry and consideration of the foregoing amendments and reconsideration of the application in view of the following remarks, which are intended to place this case in condition for allowance.

## **II. Interview Summary**

On May 26, 2006, Applicant's representative participated in a telephone interview with the Examiner to inquire as to the status of pending claims 27, 28 and 37, which was not indicated in the instant Office Action. The Examiner stated that claims 27 and 28 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 86/04088. The Examiner also stated that claim 37 stands objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

## **III. Claim 13 Is Novel over Scheicher**

At page 2, paragraph 5 of the instant Office Action, claim 13 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Scheicher (U.S. Patent No. 4,278,630). The Examiner

asserts that Scheicher anticipates claim 13 by teaching porous implants of ceramic fibers sintered together. Applicant respectfully traverses the rejection based on the amended claim.

Amended claim 13 is directed to a sintered scaffold material comprising glass fibers, wherein the glass fibers comprise **bioactive** glass having the recited composition. Scheicher fails to teach bioactive glass fibers. Scheicher discloses various types of fine inorganic fibers in a non-fibrous ceramic base substance (col. 2, line 18 to col. 4 line 55). But none of the disclosed fibers is a bioactive glass having the composition as claimed. Thus, Scheicher fails to teach or suggest each and every limitation of claim 13. Accordingly, Applicant respectfully requests withdrawal of the 35 U.S.C. § 102(b) rejection and allowance of claim 13.

#### **IV. Claims 6-7 and 11-12 Are Novel over WO 86/04088**

At page 3, paragraph 6 of the instant Office Action, claims 6-7 and 11-12 stand rejected under 35 U.S.C. § 102(b) as being anticipated by WO 86/04088. The Examiner asserts that WO 86/04088 anticipates the subject claims by teaching a porous sintered glass fiber matrix held together by an organic polymer. The Examiner is of the opinion that the claimed sintering temperatures do not provide patentability because in product-by-process claims, the patentability of the product does not depend on its method of production. Applicant respectfully traverses the rejection.

The processes recited in the subject claims do provide patentability because they produce a different product than that of WO 86/04088. Independent claim 6 is directed to a sintered glass scaffold comprising glass fibers sintered together to form the scaffold, wherein the fibers (sintered together to form the scaffold) have a **coating** of one or more biocompatible polymers or copolymers. The polymer is retained in the sintered scaffold to improve the elastic performance

of the scaffold (page 8, line 35 to page 9, line 3 and Example 3). WO 86/04088 teaches glass fiber matrix particles, which before use as a carrier of biologically active materials, are joined together at the points of contact by a **carbonized** organic binder (abstract and page 7, lines 9-13). The sintered glass fibers in the carrier of WO 86/04088 do not have a coating of polymer binder after carbonization. Specifically, WO 86/04088 teaches glass fiber matrix particles that are loosely molded into the desired structure, impregnated with an organic binder, and then heated to **substantially completely remove** (carbonize) the organic binder from the free surfaces of the structure. The carbonized organic binder imparts a bonding effect to the adjoining contact surfaces (page 7, lines 13-33). "Although the entire structure has been soaked with the organic binder, the latter is substantially completely removed from the free particle surfaces upon carbonization." (page 7, lines 33-36) Thus, WO 86/04088 fails to teach glass fibers that, having been sintered together to form a scaffold, have a polymer coating as recited in claim 6.

Claim 7 is dependent on claim 6, so claim 7 is novel for at least the same reasons as those set forth in the above paragraph. In addition, WO 86/04088 fails to teach or suggest **bioactive** glass fibers as recited in claim 7. WO 86/04088 discloses an **inert** carrier consisting of joined-together particles of a porous sintered glass fiber matrix (page 3, lines 5-15). WO 86/04088 specifically teaches that its carrier is not decomposed under the action of cells which are being divided (page 12, lines 12-13). Thus WO 86/04088 fails to teach or suggest each and every limitation of claim 7.

WO 86/04088 teaches as suitable conditions for carbonization a temperature range of about 500-700 °C, most preferably at 600 °C. These conditions are sufficient to effect complete carbonization (removal) of the organic binder (page 9, lines 1-14). On the contrary, the much lower sintering temperature ranges of dependent claim 11 (about 50 °C to about 300 °C) and

dependent claim 12 (about 100 °C to about 200 °C) do not remove the polymer coating, but serve to soften the polymer and bind the polymer-coated glass fibers together to form the scaffold of the invention (page 9, lines 28-32 and Example 3). The heating process of the present invention forms a polymer-coated glass fiber scaffold, while the heating process of WO 86/04088 removes the polymer from the glass fibers. Thus, WO 86/04088 fails to teach the product formed from the sintering processes of claims 11 and 12.

For the above reasons, WO 86/04088 fails to teach or suggest each and every limitation of claims 6-7 and 11-12. Accordingly, Applicant respectfully requests withdrawal of the 35 U.S.C. § 102(b) rejection and allowance of claims 6-7 and 11-12.

**V. Claims 13 and 14 Are Novel over WO 98/47465**

At page 3, paragraph 7 of the instant Office Action, claims 13 and 14 stand rejected under 35 U.S.C. § 102(b) as being anticipated by WO 98/47465. The Examiner is of the opinion that WO 98/47465 anticipates the subject claims by disclosing a sintered porous composite for implants comprising bioactive glass with a composition as claimed. Applicant respectfully traverses the rejection.

Independent claims 13 and 14 are directed to a sintered scaffold comprising glass fibers, wherein the glass fibers comprise bioactive glass having the recited compositions. WO 98/47465 teaches glass particles, specifically glass spheres (page 9, lines 1-26). However, WO 98/47465 fails to teach or suggest a sintered scaffold material comprising glass **fibers**. Thus, WO 98/47465 fails to teach or suggest each and every limitation of claims 13 and 14. Accordingly, Applicant respectfully requests withdrawal of the 35 U.S.C. § 102(b) rejection and allowance of claims 13 and 14.

**VI. Claims 1, 3-6, 9-10, 15-32 and 34-36 Are Not Obvious over WO 86/04088**

At page 4, paragraph 9 of the instant Office Action, claims 1, 3-6, 9-10, 15-26, 29-32 and 34-36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 86/04088. In the telephone interview summarized in section II above, the Examiner indicated that claims 27 and 28 also stand rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 86/04088. The Examiner is of the opinion that the claims are obvious over WO 86/04088. Applicant respectfully traverses the rejection. A *prima facie* case of obviousness requires three showings:

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure.

*Manual of Patent Examining Procedure*, 8<sup>th</sup> ed., § 2142. These requirements of a *prima facie* case of obviousness are not met for this rejection under 35 U.S.C. § 103(a).

The Examiner has indicated at page 2, paragraph 3 of the instant Office Action that Applicant's previous amendment of claim 1 to recite **bioactive** glass fibers was successful in overcoming the 35 U.S.C. § 102(b) rejection of claim 1 and dependent claims over Scheicher. Similarly to Scheicher, WO 86/04088 also fails to teach or suggest a sintered scaffold material comprising bioactive glass fibers. WO 86/04088 specifically discloses an **inert** carrier consisting of joined-together particles of a porous sintered glass fiber matrix (page 3, lines 5-15). Independent claims 25 and 27 have also been amended to recite bioactive glass fibers. Thus, WO 86/04088 fails to teach or suggest each and every limitation of independent claims 1, 25 and 27.

In addition, WO 86/04088 fails to disclose a sintered scaffold material having a pore size sufficient to allow ingrowth of tissue, as recited in amended claim 1. Independent claims 25 and 27 have also been amended to recite scaffold material pore size sufficient to allow ingrowth of tissue. WO 86/04088 teaches a pore size of at most about 20  $\mu\text{m}$ , with 5-10  $\mu\text{m}$  being especially preferred (page 6, lines 1-4). The present invention is directed to bone grafting materials. Large pore size is required for bone tissue growth into the scaffold material. If the pores are too small, cells cannot fit inside and cannot migrate into the scaffold. Please see attached references. Reference 1, Tables I and III, shows that scaffolds with pore sizes of less than 45  $\mu\text{m}$ , which equals 45  $\mu\text{m}$ , do not allow ingrowth of tissue. References 1 and 2 show that the minimum pore size needed to have mineralized bone growth into a ceramic scaffold is 100  $\mu\text{m}$ . Reference 3 correlates an increase in bone growth with increase in pore size, where hydroxyapatite with pore sizes of 300-600  $\mu\text{m}$  demonstrate superior osteogenic activity to hydroxyapatite with pores sizes of 50-250  $\mu\text{m}$ . References 4-8 show that high porosity is needed in order to have ingrowth of bone tissue into glass fiber matrices. Reference 4 shows that optimal pore size for bone tissue ingrowth in porous hydroxyapatite is 300-400  $\mu\text{m}$ , while smaller pore sizes of 90-120  $\mu\text{m}$  induce cartilage followed by bone formation. For the above reasons, the maximum 20  $\mu\text{m}$  pore size taught by WO 86/04088 is too small to allow ingrowth of tissue into the scaffold. For this additional reason, WO 86/04088 fails to teach each and every limitation of claim 1.

As discussed in section IV above, WO 86/04088 fails to teach a sintered glass scaffold comprising glass fibers sintered together to form the scaffold, wherein the fibers (sintered together to form the scaffold) have a **coating** of one or more biocompatible polymers or copolymers, as recited in independent claim 6. WO 86/04088 specifically discloses a carrier of glass fiber matrix particles which have been heated to **substantially completely remove**

(carbonize) the organic binder from the free surfaces of the structure (page 7, lines 13-33). Independent claims 26 and 28 also recite a sintered glass scaffold comprising glass fibers coated with polymer or copolymer. Thus, WO 86/04088 fails to teach or suggest each and every limitation of independent claims 6, 26 and 28.

Claims 3-6, 9-10, 15-24, 29-32 and 34-36 all depend from either claim 1 or claim 6, so WO 86/04088 fails to teach or suggest each and every dependent claim limitation for the same reasons as above for claims 1 and 6.

WO 86/04088 fails to provide suggestion or motivation to use bioactive glass fibers because WO 86/04088 does not disclose any *in vivo* or *in vitro* applications where the carrier induces or is affected by biological activity. WO 86/04088 does not suggest the desirability to modify its inert glass carrier, which physically immobilizes biologically active materials, to a bioactive glass carrier that induces biological activity (specification page 6, lines 31-32) or is transformed by biological activity (specification page 7, lines 6-8). In fact, WO 86/04088 teaches away from bioactive glass fibers by specifically disclosing that its carrier is not decomposed under the action of cells which are being divided (page 12, lines 12-13). Therefore, the skilled artisan would not be motivated to substitute bioactive glass fibers for the inert glass fibers taught by WO 86/04088.

WO 86/04088 also fails to provide suggestion or motivation to increase the disclosed maximum pore size of 20  $\mu\text{m}$  to a size sufficient to allow ingrowth of tissue. WO 86/04088 is directed to a carrier for immobilization of biologically active materials such as enzymes and microorganisms (abstract). WO 86/04088 teaches that fine pores are preferred because they are especially well-suited for the immobilization of biologically active material of small dimensions, such as enzymes and bacteria (page 5, lines 19-28). It is known in the art that enzymes and



prokaryotic bacteria are significantly smaller in size than the eukaryotic cells that make up human and animal tissue. Increasing the pore size to allow for ingrowth of the larger eukaryotic cells would render the carrier of WO 86/04088 unsatisfactory for its intended purpose of immobilizing enzymes and bacteria, which would more easily diffuse out of the larger pores. If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

WO 86/04088 also fails to provide suggestion or motivation to use a sintered glass fiber matrix where the glass fibers of the sintered matrix have a polymer coating. WO 86/04088 teaches away from a body of glass fibers coated with polymeric binder, stating that the polymeric binder may affect the immobilized biologically active material, and the polymeric binder may also adversely affect the porosity of the body (page 2, lines 6-30). Therefore, the skilled artisan would not be motivated by WO 86/04088 to retain the polymer coating on the glass fibers in the sintered matrix body.

For the above reasons, a *prima facie* case of obviousness cannot be made. Accordingly, Applicant respectfully requests withdrawal of the 35 U.S.C. § 103(a) rejection and allowance of claims 1, 3-6, 9-10, 15-32 and 34-36.

## **VII. Objection of Claims 8, 33 and 37**

At page 5, paragraph 10 of the instant Office Action, claims 8 and 33 stand objected to for being dependent upon rejected base claims. In the telephone interview summarized in section II above, the Examiner indicated that claim 37 also stands objected to for being dependent upon rejected base claims. Applicant gratefully acknowledges the Examiner's

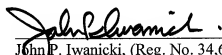
indication that claims 8, 33 and 37 would be allowable if rewritten into independent form. Applicant has therefore rewritten multiple dependent claims 8, 33 and 37 into independent form to include all of the subject matter from the first base claim, and also added new independent claims 50-52 to include all of the subject matter from the second base claim along with the subject matter of claims 8, 33 and 37, respectively. As the Examiner has admitted, the prior art does not provide for the claimed sintered scaffold material further including a biocompatible polymeric coating or film selected from the group consisting of polyglycolide, polylactide, poly- $\beta$ -hydroxybutyric acid, polydioxanone, polyvinylalcohol, polyesteramine, their copolymers and polymer blends thereof. The prior art also does not provide for the claimed sintered scaffold wherein the fibers form a mat which is attached to a membrane. Accordingly, Applicant respectfully requests withdrawal of the objection and allowance of claims 8, 33, 37 and 50-52.

### **VIII. Conclusion**

Having addressed all outstanding issues, Applicant respectfully requests entry and consideration of the foregoing amendments and reconsideration and allowance of the case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

Respectfully submitted,

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